



## UNITED STATES DEPARTMENT OF COMMERCE

## Patent and Trademark Offic

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Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/554,602 07/14/00 LAVERSANNE

R 00108

023338 HM12/0927  
DENNISON, SCHEINER SCHULTZ & WAKEMAN  
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EXAMINER

KISHORE, G

ART UNIT PAPER NUMBER

1615

DATE MAILED:

09/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>09/554,602</b>	Applicant(s) <b>Degert</b>
	Examiner <b>Gollamudi S. Kishore, Ph.D</b>	Art Unit <b>1615</b>
		
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>		
<b>Period for Reply</b>		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>three</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.		
<ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>		
<b>Status</b>		
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Jul 14, 2000</u>		
2a) <input type="checkbox"/> This action is FINAL.      2b) <input checked="" type="checkbox"/> This action is non-final.		
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.		
<b>Disposition of Claims</b>		
4) <input checked="" type="checkbox"/> Claim(s) <u>1-21</u> is/are pending in the application.		
4a) Of the above, claim(s) _____ is/are withdrawn from consideration.		
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.		
6) <input checked="" type="checkbox"/> Claim(s) <u>1-21</u> is/are rejected.		
7) <input type="checkbox"/> Claim(s) _____ is/are objected to.		
8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.		
<b>Application Papers</b>		
9) <input type="checkbox"/> The specification is objected to by the Examiner.		
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are objected to by the Examiner.		
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved.		
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.		
<b>Priority under 35 U.S.C. § 119</b>		
13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).		
a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).		
*See the attached detailed Office action for a list of the certified copies not received.		
14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).		
<b>Attachment(s)</b>		
15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)		
16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		
17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>5</u>		
18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____		
19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)		
20) <input type="checkbox"/> Other: _____		

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## **DETAILED ACTION**

**The preliminary amendment dated 7-14-00 is acknowledged.**

**Claims included in the prosecution are 1-21.**

### *Specification*

**There is no heading for the drawings in the specification.**

### *Claim Rejections - 35 USC § 112*

1. **The following is a quotation of the second paragraph of 35 U.S.C. 112:**

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. **Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

**What is being conveyed by ‘regular stack of concentric bilayers’ in claim 1? The examiner suggests ‘inhibiting’ or some other expression instead of ‘avoiding’.**

**Is the surfactant recited in claim 5 is in addition to the one recited in claim 1?**

**What is meant by ‘trapping effect’ as recited in claim 7?**

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**What is meant by agent for stabilizing said active agent comprises a second active agent' as recited in claim 15?**

**What is a leakproofing agent as recited in claim 16?**

**Claim 17 is a method of preparation claim and hence the step of how the liquid lamellar phase is prepared should be recited.**

**Claim 20 ends abruptly with 'ad defined in'.**

**The examiner suggests a careful review of the claims.**

*Double Patenting*

**3.** The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**4. Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 5,908,697.**

**Although the conflicting claims are not identical, they are not patentably distinct from each**

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**other because instant generic ‘surfactant’ includes the specific surfactant recited in the claims of said patent.**

**5. Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 6,277,404.**

**Although the conflicting claims are not identical, they are not patentably distinct from each other because instant generic liposomes encompass the liposomes recited with size ranges in the claims of said patent.**

*Claim Rejections - 35 USC § 102*

**6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

**A person shall be entitled to a patent unless --**

**(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

**7. Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by CA 2133421 of record.**

**The Canadian patent discloses multilamellar vesicles containing stacked bilayers and made from both ionic and non-ionic surfactants. The vesicles contain either hydrophobic or hydrophilic active agents and also contain a polymer (polyacrylamide) (note page 2, line 12 through page 3, line 11, page 7, Examples and claims).**

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**8. Claims 1-8 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/31194 of record.**

**WO discloses multilamellar non-phospholipid liposomes containing surfactants, retinol, tocopherol, vitamin C and other antioxidants (note the abstract, pages 9, 10, 13 and examples, Examples 7 and 8 in particular).**

**9. Claims 1-8 and 14-19 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/18601 of record.**

**WO 95 discloses multilamellar liposomes, a method of preparation forming first a lamellar liquid crystalline phase and adding water. The active agents include vitamins, hydroxy acids and others (note the abstract, page 5, examples, Example 10 in particular).**

**10. Claims 1-7 and 9-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Munechika (5,662,931).**

**Munechika discloses multilamellar liposomes containing lecithin, a surfactant and enzymes such as urokinase. The liposomes further contain, stearylamine, cholesterol and polysaccharides as stabilizers (note the abstract, columns 2-3, Examples).**

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**11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.**

**The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.**

**If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.**

**Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].**

**All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.**

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**Any inquiry of a general nature or relating to the status of this application should  
be directed to the Group receptionist whose telephone number is (703)308-1235.**



**Gollamudi S. Kishore, Ph. D**

**Primary Examiner**

**Group 1600**

*gsk*

**September 25, 2001**